AXON SYSTEMS

K061639

11. 510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of CFR 807.92.

NOV 1 2006

Summary Date: June 6, 2006

Submitter's Information:

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Trade Names: Eclipse TCD Neurovascular Workstation
Eclipse Neurological Workstation with TCD and vascular Doppler
CardioMon

Common Name: Electroencephalograph (EEG Monitor), Evoked Potential (SEP, BAEP, AEP, VEP, MEP) System, EMG Monitor, Transcranial and Vascular Doppler, Diagnostic Ultrasound Transducer

Classification Name: Electroencephalograph, Evoked Response, Electromyograph, System, Imaging, Pulsed Doppler, Ultrasonic, Diagnostic Ultrasound Transducer

Classification: Class II (Performance Standards)

Panels: Neurology, Physical Medicine, Radiology

Number:		
	882.1400	Electroencephalograph
	882.1420	Electroencephalograph (EEG) Signal Spectrum Analyzer
	890.1375	Electromyograph
	882.1870	Stimulator, Electrical, Evoked Response
	882.1890	Stimulator, Photic, Evoked Response
	882.1900	Stimulator, Auditory, Evoked Response
	892.1550	System, Imaging, Pulsed Doppler, Ultrasonic
	892.1570	Diagnostic Ultrasound Transducer

Procodes: GWQ, GWS, GWF, GWE, GWJ, IKN, IYN, ITX

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Predicate Devices Axon Systems - Eclipse Neurological Workstation (K050798)
Multigon Industries – 500P Pocket Transcranial and Vascular Doppler Spectrum Analyzer (K051739)

Description: The Eclipse Neurological Workstation with TCD and vascular Doppler, Eclipse TCD Neurovascular Workstation and CardioMon (The Systems) provide **continuous monitoring** of brain and neural pathways and intracranial and extracranial vascular blood flow intraoperatively or in the intensive care unit. The **system has been designed to meet the requirements** for **comprehensive neurological monitoring in the operating** room **and critical care areas.**

The Systems can be used to monitor neurological and vascular data using either individual or multimodality EEG, EMG, evoked potential and Doppler test protocols.

The Systems main components include: computer, internal or external Doppler, controller, digital preamplifiers, direct nerve, sensory and motor evoked potential electrical stimulators, stimulator extension modules, LED goggles and insert earphones. The Systems also provide support for the Nonin XPod pulse oximeter module and a high impedance preamplifier module to allow recording from micro electrodes.

Recording electrodes detect spontaneous or stimulus evoked electrophysiological activity and are used as inputs to the digital preamplifier. Electrophysiological signals are amplified, filtered, optically isolated and digitized. The digitized data is then routed to the digital signal processor (DSP) located in the Eclipse controller. The DSP processes the data and controls timing for the electrical, audio and visual stimulators.

The computer controls the user interface for setting parameters and the display of processed data. The computer also provides the hardware and software Doppler interface.

The TCD and vascular Doppler provide blood flow information using a spectral display and audible Doppler signal.

A built-in pulse oximeter provides pulse rate and oxygen saturation measures.

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Data from external devices, such as vital signs or other physiological monitors, can be imported to the systems display screen, allowing the operator to correlate changes in neurological function with systemic changes.

In addition, a display window may be opened to observe the surgeon's microscope view or other video inputs. The systems are network compatible for data review within the hospital and permits secure information access over the Internet.

The Systems were tested functionally using accepted laboratory test procedures.

Technologically, The Systems are similar to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Axon Systems, Inc.
% Mr. Howard Bailin
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NOV 1 2006

Re: K061639
Trade/Device Name: Eclipse TCD Neurovascular Workstation
Eclipse Neurological Workstation with TCD and Vascular Doppler
CardioMon
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF, IYN
Dated: October 16, 2006
Received: October 17, 2006

Dear Mr. Bailin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K061639

Device Name

Eclipse TCD Neurovascular Workstation
Eclipse Neurological Workstation with TCD and Vascular Doppler CardioMon

Indications for Use

The systems are intended for use to monitor sensory and motor pathways and to provide information to determine the state of blood flow in the intracranial and extracranial vascular arteries in adults. The instrument uses electroencephalography (EEG), electromyography (EMG), motor and sensory evoked potentials and nerve potentials and Doppler analysis. Transcranial stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract.

The system is used in the operating room and critical care areas to provide health care professionals with information to guide surgery and to assess a patient's neurological and vascular status.

Doppler analysis is not to be used for Obstetrics.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061639